UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

JANINE ALI, Plaintiff, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	Case No. 1:14-cv-01615-AJT-JFA Hon. Anthony J. Trenga Hon. John F. Anderson **MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTIONS TO COMPEL RESPONSES TO PLAINTIFF'S REQUESTS FOR ADMISSION**
GILDA HAGAN-BROWN, Plaintiff, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	Case No. 1:14-cv-01614-AJT-JFA Hon. Anthony J. Trenga Hon. John F. Anderson **MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTIONS TO COMPEL RESPONSES TO PLAINTIFF'S REQUESTS FOR ADMISSION**

INTRODUCTION

This motion, brought pursuant to Fed. R. Civ. P. 36(a)(6), seeks an order compelling Defendant Eli Lilly and Company ("Lilly") to respond properly to Plaintiffs' Requests for Admission ("RFAs") Nos. 3, 4, 5, and 56. As it stands, Lilly has neither admitted nor denied these RFAs. For RFA Nos. 3, 4, and 5, which ask Lilly to admit that discontinuation of Cymbalta *causes* withdrawal symptoms, Lilly re-worded the RFAs and admitted that discontinuation of Cymbalta "may be associated" with adverse symptoms. But the RFAs never asked about *association*, they asked about *causation*. By re-wording the RFA and then admitting to the re-wording, Lilly has provided a non-responsive answer. For RFA No. 56, which asks

Lilly to admit that it bears responsibility for the content of the Cymbalta label at all times, Lilly simply objects. Lilly claims that the term "responsibility" is vague and ambiguous and that the question calls for a legal conclusion. These objections are unfounded. Not only is "responsibility" an easily understood term, even for a pharmaceutical company, the RFA does not call for a pure legal question—it calls for a legal opinion as it applies to the facts of this case, which is specifically allowed for by Federal Rule of Civil Procedure 36(a).

BACKGROUND

Plaintiffs served their First Set of Requests for Admission on February 4, 2015. (*See* 14-cv-01615, Wisner Decl., Exhibits 2-A, 4-A, 14-cv-01615, Dkt. 37-4). On February 23, 2015, Lilly served its objections (*id.*, Exhibits 2-B, 4-B), and on March 9, 2015, Lilly served its responses. (*Id.*, Exhibits 2-C, 4-C.) On March 13, 2015, Plaintiffs' counsel sent a letter to Lilly outlining deficiencies with Lilly's responses to several Requests for Admission ("RFAs") including RFA Nos. 3, 4, 5, and 56. This prompted a 2 ½ hour meet-and-confer on March 17, 2015 wherein Lilly's responses to RFA Nos. 3, 4, 5, and 56 were discussed. Despite a good faith effort to resolve the discovery dispute, Lilly refused to supplement and/or respond to these RFAs and the parties reached an impasse.

LEGAL STANDARD

"Admissions are sought, first to facilitate proof with respect to issues that cannot be eliminated from the case, and secondly, to narrow the issues by eliminating those that can be." Fed. R. Civ. P. 36 Advisory Committee's Notes, 1970 Amendment. "'Parties may not view requests for admission as a mere procedural exercise requiring minimally acceptable conduct. They should focus on the goal of the Rules, full and efficient discovery, not evasion and word play.'" *House v. Giant of Maryland LLC*, 232 F.R.D. 257, 259 (E.D. Va. 2005) (quoting

Marchand v. Mercy Med. Ctr., 22 F.3d 933, 936–37 (9th Cir.1994)).

An RFA may request that a party admit "the truth of any matters within the scope of Rule 26(b)(1) relating to. . . facts, the application of law to fact, or opinions *about either*[.]" Fed. R. Civ. P. 36(a)(1) (emphasis added). "When confronted with a Rule 36 request for admission, the responding party must either object or answer." *House*, 232 F.R.D. at 259. And, in answering, the party must either admit the request or:

> [T]he answer must specifically deny it or state in detail why the answering party cannot truthfully admit or deny it. A denial must fairly respond to the substance of the matter; and when good faith requires that a party qualify an answer or deny only a part of a matter, the answer must specify the part admitted and qualify or deny the rest.

Fed. R. Civ. P. 36(a)(4).

A party may file a motion to determine the sufficiency of an answer to an RFA and "unless the Court finds the objection justified, it must order that an answer be served." Fed. R. Civ. P. 36(a)(6). The Court may, in its discretion, upon determining that an answer is insufficient, "order either that the matter is admitted or that an amended answer be served." *Id.*

ARGUMENT

I. RFAs 3, 4, and 5

Plaintiffs' RFA Nos. 3, 4, and 5 state:

> **Request for Admission No. 3:**
> Admit that the abrupt discontinuation of a daily dose of 30 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.
>
> **Request for Admission No. 4:**
> Admit that the abrupt discontinuation of a daily dose of 40 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.
>
> **Request for Admission No. 5:**
> Admit that the abrupt discontinuation of a daily dose of 60 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

(14-cv-01615, Wisner Decl., Exhibits 2-A, 4-A, 14-cv-01615, Dkt. 37-4.) These RFAs seek to narrow an important issue in this litigation, i.e., whether the abrupt discontinuation of a daily dose of Cymbalta can ***cause*** adverse symptoms resulting from the discontinuation. Lilly responded:

> Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the abrupt discontinuation of a [30/40/60] mg/day dose of Cymbalta may be associated with certain adverse symptoms, which are listed in Cymbalta's U.S. Label, but further notes that many such patients do not experience such symptoms upon discontinuation.

(*Id.*, Exhibits 2-C, 4-C, 14-cv-01615, Dkt. 37-4). Plaintiffs submit that this response is inadequate.

The RFAs are asking Lilly to admit that there is a ***causal connection*** between discontinuation and adverse symptoms, not whether discontinuation "may be associated with certain adverse symptoms."[1] There is an important factual difference between association and causation. *E.g.*, *Amorgianos v. Nat'l R.R. Passenger Corp.*, 137 F. Supp. 2d 147, 168 (E.D.N.Y. 2001) *aff'd* 303 F.3d 256 (2d Cir. 2002) ("Even when an appropriately designed study yields evidence of a statistical *association* between a given substance and a given health outcome, epidemiologists generally do not accept such an association by itself as proof of a causal relationship between the exposure and the outcome."). Lilly's response, therefore, is materially deficient. Instead of responding to the RFA asked, Lilly simply reworded the RFA and admitted to the rewording. This is improper and renders Lilly's response non-responsive. *E.g.*, *Helget v. City of Hays, Kans.*, 300 F.R.D. 496, 502 (D. Kan. 2014) ("Defendant's substitution of the word "told" for "discussed" in the response was an improper alteration of the language of Plaintiff's

[1] Nor did the RFAs ask Lilly to "note[] that many such patients do not experience such symptoms upon discontinuation."

Request. . . As Plaintiff noted, and as the Court acknowledges, "discussed" and "told" have different definitions.").

These RFAs are not asking Lilly to admit to anything particularly ground-breaking. These RFAs simply ask Lilly to admit that discontinuing Cymbalta can cause withdrawal effects—a fact that should not be in material dispute. Accordingly, Plaintiffs respectfully ask this Court to enter an order compelling Lilly to admit or deny RFA Nos. 3, 4, and 5, as worded by the Plaintiffs, or else deem the RFAs admitted. *See* Fed. R. Civ. P. 36(a)(6)

II. RFA No. 56

Plaintiffs' RFA No. 56 states:

> Admit that YOU, not the FDA, bear responsibility for the content of the CYMBALTA LABEL at all times.

(14-cv-01615, Wisner Decl., Exhibits 2-A, 4-A, 14-cv-01615, Dkt. 37-4.) This request was fashioned from a direct quote from the seminal Supreme Court decision *Wyeth v. Levine*, which states:

> Wyeth suggests that the FDA, rather than the manufacturer, bears primary responsibility for drug labeling. Yet through many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that **the manufacturer bears responsibility for the content of its label at all times**. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market.

555 U.S. 555, 570-71 (2009) (emphasis added). The purpose of this request is to establish that, because Lilly controls the Cymbalta brand, it has assumed the responsibility to prepare and update a Cymbalta label. This admission is vital because it limits Lilly's ability to hide behind the fact that Cymbalta was "FDA-approved" in depositions of potential witnesses and when this case is tried to a jury.

In response to this RFA, Lilly merely directs Plaintiffs to its objections (14-cv-01615,

Wisner Decl., Exhibits 2-C, 4-C, 14-cv-01615, Dkt. 37-4), which state:

> Lilly objects to this Request for Admission because its use of the term "responsibility" is vague and ambiguous. Lilly further objects to this Request to the extent that it calls for a legal conclusion.

(*Id.*, Exhibits 2-B, 4-B.) Plaintiffs submit that both of these objections are invalid.

First, the term "responsibility" is not vague or ambiguous. According to Black's Law Dictionary, responsibility is the "quality, state, or condition of being answerable or accountable[.]" RESPONSIBILITY, Black's Law Dictionary (10th ed. 2014). English Oxford Dictionary defines responsibility as:

> 1. The state or fact of having a duty to deal with something or of having control over someone . . .
>
> 1.1 The state or fact of being accountable or to blame for something . . .
>
> 1.2 The opportunity or ability to act independently and make decisions without authorization . . .
>
> 1.3 A thing that one is required to do as part of a job, role, or legal obligation . . .
>
> 1.4 A moral obligation to behave correctly toward or in respect of . . .

Oxford Dictionaries, *Responsibility*, http://www.oxforddictionaries.com/us/definition/american_english/responsibility (accessed Mar. 26, 2015). Any of these definitions would apply here. Lilly's objection that it does not understand what the term responsibility means is unfounded.

Second, Lilly's refusal to admit or deny this RFA because "it calls for a legal conclusion" is misplaced. Rule 36 specifically contemplates that an RFA may related to "facts, the *application of law to fact*, or opinions *about either*[.]" Fed. R. Civ. P. 36(a)(1) (emphasis added). This RFA asks whether Lilly bears responsibility for the content of the Cymbalta label at all times, a question that implicates the fact that Lilly controls the Cymbalta brand as its

manufacturer and the legal issue of the scope of its responsibility for the content of the label. This RFA is asking Lilly to admit to the scope of its authority and control over the Cymbalta label, a necessary element in a failure-to-warn case. In other words, the RFA is asking for Lilly's view on an application of fact to law.

Asking a party to admit to the scope its legal obligation with regard to a specific product is precisely the type of application of law to fact contemplated by Rule 36. The advisory committee note to the 1970 amendments explains:

> For example, an admission that an employee acted in the scope of his employment may remove a major issue from the trial. In *McSparran v. Hanigan,* plaintiff admitted that "the premises on which said accident occurred, were occupied or under the control" of one of the defendants, [225 F.Supp. 628, 636 (E.D.Pa.1963)]. This admission, involving law as well as fact, removed one of the issues from the lawsuit and thereby reduced the proof required at trial.

Fed. R. Civ. P. 36, advisory committee note to the 1970 amendments; *see also S.E.C. v. Goldstone*, 300 F.R.D. 505, 523 (D.N.M. 2014) (giving an in-depth analysis of the distinction between an RFA requesting a purely legal issue and an RFA seeking an application of law to fact). In *McSparran*, the issue concerning the scope of an employee's activity was, by definition, a question of law tethered to facts of that case, because there was a question of whether the employer could be liable for its employee's conduct. Resolving whether the employer was responsible for the employees conduct was, thus, an appropriate RFA. The same fact-to-law analysis applies here. RFA No. 56 is asking Lilly to admit to being responsible for the content of the Cymbalta label, just as the plaintiff in *McSparran* sought an admission that the employer was responsible for the conduct of its employee. *See, e.g.*, *Brown v. Montoya*, No. CIV 10-0081 JB/ACT, 2013 WL 1010390, at *24 (D.N.M. Mar. 8, 2013) ([T]he RFAs here are also trying to determine, factually, if individual Defendants are individually involved in, or responsible for, ensuring their office's compliance with laws . . . They are not a question taken from the

Multistate Bar Examination in true/false form, asking the Defendants to admit the truth of the bar exam question."). In answering this RFA, Lilly must examine the law, examine its responsibilities with regard to Cymbalta, and respond with its opinion. If Lilly does not believe it bears responsibility for the content of the Cymbalta label at all times, then that fact will be very relevant, and Plaintiffs will need to conduct discovery on the issue. Conversely, if Lilly admits that it does bear responsibility for the content of the Cymbalta label then it will focus this litigation. In either case, this is precisely the type of question that a party should either admit or deny.

Plaintiffs respectfully request that the Court compel Lilly to respond to RFA No. 56 or else deem the RFA admitted. *See* Fed. R. Civ. P. 36(a)(6).

CONCLUSION

For the forgoing reasons, Plaintiffs respectfully request that this Court enter an order compelling Lilly to respond to RFA Nos. 3, 4, 5, and 56 within seven days or else the RFAs will be deemed admitted.

DATED: March 27, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 27th[th] day of March, 2015, a true copy of the foregoing MOTION TO COMPEL was filed electronically with the Clerk of Court using the CM/ECF system, which will send a notification of such filing to the following:

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